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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,083	09/17/1999	DAVID CALDERWOOD	BBIC-043/A	1842

7590 03/03/2008  
GAYL B O'BRIEN  
ABBOTT BIORESEARCH CENTER  
100 RESEARCH DRIVE  
WORCESTER, MA 01605-4314

EXAMINER
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RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

MAIL DATE	DELIVERY MODE
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03/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/399,083	CALDERWOOD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11, 46 and 48-52 is/are pending in the application.
- 4a) Of the above claim(s) 48-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-11, 46, 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1624

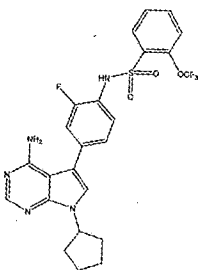
**DETAILED ACTION**

This office action is in response to the amendment filed on October 31, 2007.

Claims 1-8, 11, 46 and 48-52 are pending in this application.

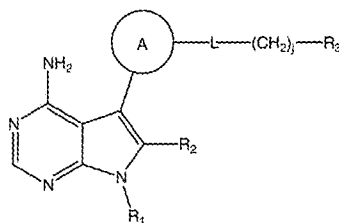
***Election/Restrictions***

Applicant's elected the species: N-(4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-fluorophenyl)-2-(trifluoromethoxy)-1-benzenesulfonamide in the response filed on May 7, 2001. The species is depicted below for convenience:



The species reads on claims 46 and 52.

The elected species was not found in the prior art, the search was expanded to the genus of structural formula of claim 1:



wherein:

ring A is phenyl substituted with substituents listed in claim 1;

L is -NHSO<sub>2</sub>- or -NHCO<sub>2</sub>-;

Art Unit: 1624

R<sub>3</sub> is substituted or unsubstituted phenyl; and

R<sub>1</sub> and R<sub>2</sub> are as defined in the claims and art was found. Claims 48-51 and the generic portion of claims 1-8 and 10-11 drawn to compound other than those falling within the above searched/expanded subgenus are withdrawn from consideration as being drawn to nonelected inventions (see MPEP § 803.02).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In claim 1, it is recited that “R<sub>d</sub>, R<sub>e</sub> and the nitrogen atom to which they are attached together form .... heterobicyclic group; R<sub>d</sub> and R<sub>e</sub> are each, independently, alkanoyl or –K-D” (see page 3, lines 13-16):

R<sub>d</sub>, R<sub>e</sub> and the nitrogen atom to which they are attached together form a 3, 4, 5, 6 or 7-membered substituted or unsubstituted heterocycloalkyl or substituted or unsubstituted heterobicyclic group; ~~or~~

R<sub>d</sub> and R<sub>e</sub> are each, independently, ~~H, alkyl,~~ alkanoyl or –K-D;

The above definitions of R<sub>d</sub> and R<sub>e</sub> are confusing because it is not clear how the two terms together with the nitrogen atom form a cyclic group as well as independently represent other groups. The two definitions are not separated by -- or -- to be in the alternative.

Art Unit: 1624

2. In claim 1, in the definition of L, the first term "N(C(O)OR)-" is not represented as a bivalent group. Since L represents a bivalent group, the above term should be written as -N(C(O)OR)- --.
3. In claim 1, in the definition of L, the term "-CH(NR)-" is not understood. It is not clear if the term is intended to represent -CH-NR- or -CH(=NR)-. In either situations, one of the atoms of the chain, i.e., nitrogen or carbon (respectively) will either have an open valency or more attachments than permissible. The specification does not provide any explanation or an example having this group for L.
4. In claim 1, it is recited that "or L is -NRC(O)-, -NRC(O)O-, -S(O)<sub>2</sub>NR-, -C(O)NR- or -OC(O)NR-, and R<sub>3</sub> is substituted or unsubstituted alkyl, substituted or unsubstituted alkenyl or substituted or unsubstituted aralkyl; provided that j is 0 when L is -CH<sub>2</sub>NR-, -C(O)NR- or -NRC(O)- and R<sub>3</sub> is azacycloalkyl or azaheteroaryl" (see page 5, lines 3-7):  

heterocycloalkyl; or L is -NRC(O)-, -NRC(O)O-, -S(O)<sub>2</sub>NR-, -C(O)NR- or -OC(O)NR-, and R<sub>3</sub> is substituted or unsubstituted alkyl, substituted or unsubstituted alkenyl or substituted or unsubstituted aralkyl;  
provided that j is 0 when L is -CH<sub>2</sub>NR-, -C(O)NR- or -NRC(O)- and R<sub>3</sub> is azacycloalkyl or azaheteroaryl;

The above recitation is very confusing. The proviso statement lacks antecedent basis because when L is -C(O)NR- or -NRC(O)-, R<sub>3</sub> is defined to be alkyl, alkenyl or aralkyl and therefore, it is not understood how R<sub>3</sub> is recited to be azacycloalkyl or azaheteroaryl. There is no basis for this in the claim. Further, the claim defines R<sub>3</sub> to be cycloalkyl, aromatic group, heteroaromatic group or heterocycloalkyl group (see page 5, line s1-3) and it is not clear what is intended by the recitation "R<sub>3</sub> is azacycloalkyl or azaheteroaryl".

Art Unit: 1624

5. Claim 5 recites the limitation "ring A is selected from ... a substituted naphthyl, ... and a substituted indole" in lines 2-3. There is insufficient antecedent basis for this limitation in claim 1 on which claim 5 is dependent. According to claim 1, 'ring A is a six membered aromatic ring or a five or six membered heteroaromatic ring which is substituted with one or more substituents' and the claim does not define ring A to include the above bicyclic rings having nine or ten ring atoms.
6. In claim 11, it is recited "L is  $\text{-NHSO}_2\text{R-}$ ,  $\text{-NHC(O)O-}$  or  $\text{-NHC(O)R-}$ ; wherein R is H, an acyl group, ...". This recitation is confusing because the terms  $\text{-NHSO}_2\text{R-}$  and  $\text{-NHC(O)R-}$  do not appear to represent bivalent groups because R is a monovalent substituent group such as H. For example,  $\text{-NHC(O)R-}$  is  $\text{-NHCH(O)}$  when R is H and does not represent a bivalent linking group as required for the structural formula of the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

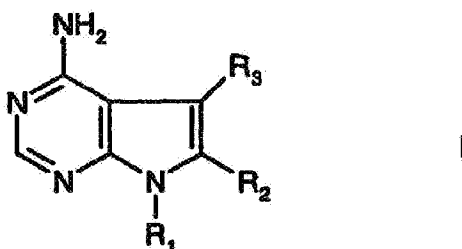
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1624

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calderwood et al., WO 98/41525. The reference teaches a generic group of compounds which embraces applicant's instantly claimed compounds. See formula I in page 2 (depicted below for convenience):



wherein R<sub>3</sub> is represented by formula (a)



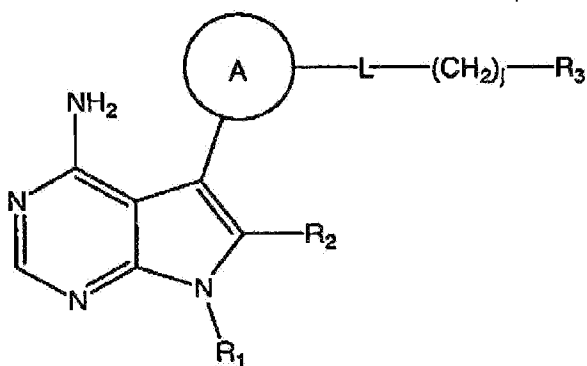
wherein the phenyl ring of formula (a) is optionally further substituted (see page 3, lines 6-9 and 25-33 and page 4 lines 1-2);

wherein the term optionally substituted phenyl means phenyl optionally substituted by one or more of the following: a) a C<sub>1-6</sub> alkyl group, b) a C<sub>1-6</sub> alkoxy group, c) phenoxy, d) hydroxy, e) phenyl C<sub>1-6</sub> alkyl, f) halo, g) a group of formula NR<sub>10</sub>R<sub>11</sub> in which R<sub>10</sub> and R<sub>11</sub> independently represent hydrogen, a C<sub>1-6</sub> alkyl group, phenyl, a C<sub>1-6</sub> alkanoyl group, a (C<sub>1-6</sub> alkoxy)carbonyl group, 5-hydroxy-1-phenyl-3-pyrazolyl or benzoyl which is optionally substituted by C<sub>1-6</sub> alkyl, C<sub>1-6</sub> alkoxy or halo h) a group of formula -COR<sub>9</sub> in which R<sub>9</sub> represents hydroxy, a C<sub>1-6</sub> alkoxy group, phenoxy or a group of formula NR<sub>10</sub>R<sub>11</sub> in which R<sub>10</sub> and R<sub>11</sub> are as previously defined, i) a phthalimido group optionally substituted by halo, j) the phenyl ring is benz fused forming naphthyl or k) nitro.

Art Unit: 1624

A is  $\text{NHSO}_2$ , ....  $\text{NHCO}_2$ , ... (page 3, line 10) and  $\text{R}_5$  is optionally substituted phenyl. The reference further discloses several species that fall within the above genus, see pages 10-14, particularly page 14, lines 9-14 and 22-23. The compounds are taught to be useful as pharmaceutical therapeutic agents having protein kinase inhibition activity, see the entire document.

The instant claim 1 is drawn to a compound represented by structural formula:



wherein Ring A is a substituted six membered aromatic ring, e.g., substituted phenyl, which is substituted with one or more substituents selected from the group consisting of ...  $\text{R}_c$  wherein  $\text{R}_c$  is hydrogen;

L can be  $-\text{NRC}(\text{O})\text{O}-$  wherein R is H;

j can be 0; and

$\text{R}_3$  can be an optionally substituted aromatic group, e.g., optionally substituted phenyl.

Independent claim 11 recites the same structure wherein Ring A is a phenyl substituted with one or more substituents selected from the group consisting of aliphatic group (e.g., alkyl); a halogen, etc.; L is  $-\text{NHC}(\text{O})\text{O}-$ ; j can be 0; and  $\text{R}_3$  can be an optionally substituted aromatic group, e.g., optionally substituted phenyl.



As can be seen from the description of both the reference genus and the claimed genus, it is evident that the instant claims encompass the reference genus. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as pharmaceutical therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'claims 1, 3 and 6 have been amended to delete moieties taught in WO 98/41525 as substituents for the phenyl ring from ring A', however, the substituents for ring A continue to include R<sub>c</sub> which is defined to be H and therefore, as per the claims ring A can be an unsubstituted phenyl and thus, the claims continue to be generically encompass the reference disclosed genus and/or species.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Art Unit: 1624

*Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10-11, 46 and 52 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-63 of U.S. Patent No. 6,713,474. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims substantially overlap the reference claims. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the reference disclosed compounds and recite a subgenus around the disclosed species, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the reference disclosed compounds, i.e., as therapeutic agents.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

Art Unit: 1624

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Deepak Rao/  
Primary Examiner  
Art Unit 1624**

March 3, 2008